

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: Gao, Ping *et al.*) ATTORNEY DOCKET NO.: C-3407/1/US
SERIAL NO.: 10/047,222) GROUP ART UNIT: 1614
FILED: January 15, 2002) EXAMINER: Unknown
TITLE: PHARMACEUTICAL COMPOSITION HAVING REDUCED
TENDENCY FOR DRUG CRYSTALLIZATION
DATE: June 10, 2002

CERTIFICATE OF MAILING

I hereby certify that this Information Disclosure Statement is being deposited with the United States Postal Service as First Class Mail in three (3) boxes addressed to: Assistant Commissioner for Patents, Washington, DC 20231 on JUNE 10, 2002.


Mary Katriadakis

Assistant Commissioner for Patents
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Sir:

INFORMATION DISCLOSURE STATEMENT, UNDER 37 CFR §1.97(b)

Applicants hereby submit copies of patents, publications and/or other information of which they are aware and which may be related to the examination of this application, and in respect of which there may be a duty to disclose under 37 CFR § 1.56. A list of all enclosed documents is provided in a Form PTO-1449, transmitted herewith. Due to the volume of documents listed, the documents are being submitted under separate cover in three boxes. A concise explanation of the relevance of each foreign language document listed in Form PTO-1449 is provided in Applicant's specification. Presentation of documents listed on enclosed Form PTO-1449 is not an admission that any listed



document is prior art under the Patent Statutes and the right is reserved to antedate any material described in the listed documents by a showing under 37 C.F.R. § 1.131 or otherwise.

This information disclosure statement is being filed within three months of the filing date of the above-cited patent application or prior to the mailing of a first Office action on the merits, in accordance with 37 CFR § 1.97(b). Accordingly, Applicants respectfully request that the statement be considered by the Office in the course of prosecution of the application. No fee is believed payable; however, if it is determined that a fee is payable, please charge Deposit Account No. 19-1025.

The filing of this information disclosure statement shall not be construed as a representation that a search has been made (37 CFR § 1.97(g)), an admission that the information cited is or is considered to be material to patentability, or that no other material information exists.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "David B. Fournier".

David B. Fournier
Agent for Applicant
Registration No. P-51,696
Tel. 847-581-5144

Address correspondence to:
Pharmacia Corporation
Corporate Patent Department
800 N. Lindbergh Boulevard - 04E
St. Louis, MO 63167

Enclosures:
Form PTO-1449
Copies of cited documents (provided in 3 separate boxes)
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Form PTO-1449
(R v. 8-88)

U.S. Department of Commerce
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Attorney Docket No.

Serial No.

C-3407/1/U.S.

10/047,222

Applicant

Gao *et al.*

Filing Date

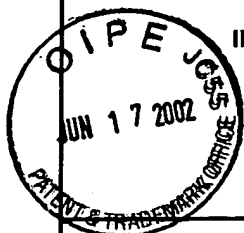
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INFORMATION DISCLOSURE STATEMENT

(Use several sheets if necessary)



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Examiner Initial*	Patent Number	Issue Date	Name	Class	Subclass	Filing Date If Appropriate
	4,250,997	Feb 17, 1981	Bodenmann <i>et al.</i>	206	528	
	5,264,223	Nov 23, 1993	Yamamoto <i>et al.</i>	424	451	
	5,344,991	Sep 06, 1994	Reitz <i>et al.</i>	568	34	
	5,380,738	Jan 10, 1995	Norman <i>et al.</i>	514	374	
	5,393,790	Feb 28, 1995	Reitz <i>et al.</i>	514	709	
	5,401,765	Mar 28, 1995	Lee	548	406	
	5,418,254	May 23, 1995	Huang <i>et al.</i>	514	604	
	5,420,343	May 30, 1995	Koszyk <i>et al.</i>	562	468	
	5,434,178	Jul 18, 1995	Talley <i>et al.</i>	514	506	
	5,436,265	Jul 25, 1995	Black <i>et al.</i>	514	420	
	5,466,823	Nov 14, 1995	Talley <i>et al.</i>	548	377.1	
	5,474,995	Dec 12, 1995	Ducharme <i>et al.</i>	514	241	
	5,475,018	Dec 12, 1995	Lee <i>et al.</i>	514	406	
	5,486,534	Jan 23, 1996	Lee <i>et al.</i>	514	406	
	5,510,368	Apr 23, 1996	Lau <i>et al.</i>	514	419	
	5,521,213	May 28, 1996	Prasit <i>et al.</i>	514	443	
	5,536,752	Jul 16, 1996	Ducharme <i>et al.</i>	514	602	
	5,543,297	Aug 06, 1996	Cromlish <i>et al.</i>	435	25	
	5,547,975	Aug 20, 1996	Talley <i>et al.</i>	514	406	
	5,550,142	Aug 27, 1996	Ducharme <i>et al.</i>	514	365	
	5,552,422	Sep 03, 1996	Gauthier <i>et al.</i>	514	368	
	5,585,504	Dec 17, 1996	Desmond <i>et al.</i>	549	323	
	5,593,992	Jan 14, 1997	Adams <i>et al.</i>	514	235.8	
	5,596,008	Jan 21, 1997	Lee	514	347	
	5,604,253	Feb 18, 1997	Lau <i>et al.</i>	514	415	
	5,604,260	Feb 18, 1997	Guay <i>et al.</i>	514	605	
	5,616,458	Apr 01, 1997	Lipsky <i>et al.</i>	435	4	
	5,616,601	Apr 01, 1997	Khanna <i>et al.</i>	514	399	
	5,620,999	Apr 15, 1997	Weier <i>et al.</i>	514	398	
	5,633,272	May 27, 1997	Talley <i>et al.</i>	514	378	
	5,639,780	Jun 17, 1997	Lau <i>et al.</i>	514	419	
	5,643,933	Jul 01, 1997	Talley <i>et al.</i>	514	372	
	5,658,903	Aug 19, 1997	Adams <i>et al.</i>	514	235.8	
	5,668,161	Sep 16, 1997	Talley <i>et al.</i>	514	365	
	5,670,510	Sep 23, 1997	Huang <i>et al.</i>	514	278	
	5,677,318	Oct 14, 1997	Lau	514	361	

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	5,686,460	Nov 11, 1997	Nicolaï et al.	514	277	
	5,686,470	Nov 11, 1997	Weier et al.	514	334	
	5,696,143	Dec 09, 1997	Talley et al.	514	403	
	5,710,140	Jan 20, 1998	Ducharme et al.	514	91	
	5,716,955	Feb 10, 1998	Adams et al.	514	235.8	
	5,723,485	Mar 03, 1998	Güngör et al.	514	415	
	5,739,166	Apr 14, 1998	Reitz et al.	514	602	
	5,741,798	Apr 21, 1998	Lazer et al.	514	309	
	5,756,123	May 26, 1998	Yamamoto et al.	424	451	
	5,756,499	May 26, 1998	Adams et al.	514	235.8	
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	5,760,068	Jun 02, 1998	Talley et al.	514	403	
	5,776,967	Jul 07, 1998	Kreft et al.	514	411	
	5,783,597	Jul 21, 1998	Beers et al.	514	447	
	5,789,413	Aug 04, 1998	Black et al.	514	255	
	5,807,873	Sep 15, 1998	Nicolaï et al.	514	336	
	5,817,700	Oct 06, 1998	Dube et al.	514	768	
	5,830,911	Nov 03, 1998	Failli et al.	514	411	
	5,849,943	Dec 15, 1998	Atkinson et al.	560	8	
	5,859,036	Jan 12, 1999	Sartori et al.	514	369	
	5,861,419	Jan 19, 1999	Dube et al.	514	334	
	5,866,596	Feb 02, 1999	Sartori et al.	514	376	
	5,869,524	Feb 09, 1999	Failli	514	473	
	5,869,660	Feb 09, 1999	Adams et al.	544	122	
	5,883,267	Mar 16, 1999	Rossen et al.	549	319	
	5,892,053	Apr 06, 1999	Zhi et al.	548	377.1	
	5,922,742	Jul 13, 1999	Black et al.	514	345	
	5,929,076	Jul 27, 1999	Adams et al.	514	252	
	5,932,598	Aug 03, 1999	Talley et al.	514	341	
	5,935,990	Aug 10, 1999	Khanna et al.	514	423	
	5,945,539	Aug 31, 1999	Haruta et al.	548	235	
	5,958,978	Sep 28, 1999	Yamazaki et al.	514	567	
	5,968,958	Oct 19, 1999	Guay et al.	514	337	
	5,972,950	Oct 26, 1999	Nicolaï	514	277	
	5,973,191	Oct 26, 1999	Marnett et al.	560	142	

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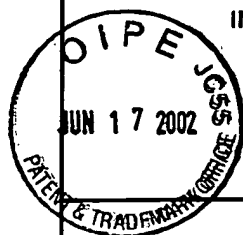
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	5,993,858	Nov 30, 1999	Crison et al.	424	490	
	5,994,381	Nov 30, 1999	Haruta et al.	514	374	
	6,002,014	Dec 14, 1999	Haruta et al.	548	235	
	6,004,960	Dec 21, 1999	Li et al.	514	247	
	6,005,000	Dec 21, 1999	Hopper et al.	514	473	
	6,020,343	Feb 01, 2000	Belley et al.	514	309	Jun 15, 1998
	6,020,347	Feb 01, 2000	De Laszlo et al.	514	331	Nov 13, 1998
	6,034,256	Mar 07, 2000	Carter et al.	549	456	Apr 17, 1998
	6,040,319	Mar 21, 2000	Corley et al.	514	334	Apr 23, 1999
	6,040,450	Mar 21, 2000	Davies et al.	546	256	Sep 15, 1998
	6,046,208	Apr 04, 2000	Adams et al.	514	274	Jul 01, 1998
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	6,057,319	May 02, 2000	Black et al.	514	242	Oct 02, 1998
	6,063,804	May 16, 2000	De Nanteuil et al.	514	411	Nov 25, 1998
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	6,133,292	Oct 17, 2000	Wang et al.	514	336	Oct 16, 1998

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	200042711	Jan 04, 2001	Australia	A61K	031/415	
	200042730	Jan 04, 2001	Australia	A61K	031/52	
	200043736	Jan 04, 2001	Australia	A61K	031/522	
	0 211 079	Aug 14, 1986	EPO	A61K	7/00	
	0 799 823	Oct 08, 1997	EPO	C07D	207/32	
	0 846 689	Jun 10, 1998	EPO	C07D	235/08	
	0 863 134	Sep 09, 1998	EPO	C07C	317/24	
	0 919 228	Jun 02, 1999	EPO	A61K	9/48	
	0 985 666	Mar 15, 2000	EPO	C07D	209/40	
	1 029 539	Aug 23, 2000	EPO	A61K	9/48	

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						Yes	No
	WO 94/15932	Jul 21, 1994	WIPO	C07D	333/18		
	WO 96/05812	Feb 29, 1996	WIPO	A61K	9/52		
	WO 96/19469	Jun 27, 1996	WIPO	C07D	307/58		
	WO 96/26921	Sep 06, 1996	WIPO (in Japanese)	C07C	317/44		x
	WO 96/31509	Oct 10, 1996	WIPO	C07D	471/04		
	WO 96/36623	Nov 21, 1996	WIPO	C07D	307/60		
	WO 96/38418	Dec 05, 1996	WIPO	C07D	231/12		
	WO 97/03953	Feb 06, 1997	WIPO (in German)	C07C	311/39		x
	WO 97/10840	Mar 27, 1997	WIPO (in Japanese)	A61K	38/14		x
	WO 97/13755	Apr 17, 1997	WIPO	C07D	231/12		
	WO 97/13767	Apr 17, 1997	WIPO (in German)	C07D	409/14		x
	WO 97/25048	Jul 17, 1997	WIPO	A61K	31/505		
	WO 97/30030	Aug 21, 1997	WIPO (in Japanese)	C07D	209/08		x
	WO 97/34882	Sep 25, 1997	WIPO	C07D	263/38		
	WO 97/35537	Oct 02, 1997	WIPO	A61J	3/07		
	WO 97/46524	Dec 11, 1997	WIPO	C07D	207/32		
	WO 98/04527	Feb 05, 1998	WIPO	C07D	209/88		
	WO 98/06708	Feb 19, 1998	WIPO	C07D	261/08		
	WO 98/07425	Feb 26, 1998	WIPO	A61K	31/44		
	WO 98/17292	Apr 30, 1998	WIPO	A61K	35/78		
	WO 98/21195	May 22, 1998	WIPO	C07D	307/60		
	WO 98/22457	May 28, 1998	WIPO	C07D	401/04		
	WO 98/32732	July 30, 1998	WIPO	C07C	311/29		
	WO 98/41516	Sep 24, 1998	WIPO	C07D	307/60		
	WO 98/43966	Oct 08, 1998	WIPO	C07D	307/58		
	WO 98/45294	Oct 15, 1998	WIPO	C07D	471/04		
	WO 98/47871	Oct 29, 1998	WIPO	C07D	213/61		
	WO 99/01130	Jan 14, 1999	WIPO	A61K	31/44		
	WO 99/01131	Jan 14, 1999	WIPO	A61K	31/445		
	WO 99/01452	Jan 14, 1999	WIPO	C07D	403/04		
	WO 99/01455	Jan 14, 1999	WIPO	C07D	487/20		
	WO 99/10331	Mar 04, 1999	WIPO	C07D	237/14		
	WO 99/10332	Mar 04, 1999	WIPO	C07D	237/14		
	WO 99/11605	Mar 11, 1999	WIPO	C07C	229/42		
	WO 99/12930	Mar 18, 1999	WIPO	C07D	487/04		
	WO 99/14195	Mar 25, 1999	WIPO	C07D	213/74		
	WO 99/14205	Mar 25, 1999	WIPO	C07D	263/38		

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						Yes	No
	WO 99/15505	Apr 01, 1999	WIPO	C07D	231/16		
	WO 99/23087	May 14, 1999	WIPO	C07D	307/58		
	WO 99/24404	May 20, 1999	WIPO	C07D	213/73		
	WO 99/25695	May 27, 1999	WIPO	C07D	231/12		
	WO 99/35130	Jul 15, 1999	WIPO	C07D	209/18		
	WO 99/61016	Dec 02, 1999	WIPO (in Japanese)	A61K	31/40		x
	WO 99/61436	Dec 02, 1999	WIPO (in Japanese)	C07D	401/04		x
	WO 99/62884	Dec 09, 1999	WIPO (in Spanish)	C07D	231/06		x
	WO 99/64415	Dec 16, 1999	WIPO	C07D	409/10		
	WO 00/01380	Jan 13, 2000	WIPO (in German)	A61K	31/165		x
	WO 00/08024	Feb 17, 2000	WIPO (in Spanish)	C07D	471/04		x
	WO 00/10993	Mar 02, 2000	WIPO	C07D	311/30		
	WO 00/13684	Mar 16, 2000	WIPO	A61K	31/00		
	WO 00/18377	Apr 06, 2000	WIPO	A61K	9/48		
	WO 00/18741	Apr 06, 2000	WIPO	C07D	231/16		
	WO 00/18753	Apr 06, 2000	WIPO	C07D	309/38		
	WO 00/23426	Apr 27, 2000	WIPO (in Spanish)	C07D	233/64		x
	WO 00/24719	May 04, 2000	WIPO	C07D	237/14		
	WO 00/26216	May 11, 2000	WIPO	C07D	471/04		
	WO 00/27367	May 18, 2000	WIPO	A61K	9/48		
	WO 00/28976	May 25, 2000	WIPO	A61K	9/48		
	WO 00/31072	Jun 02, 2000	WIPO	C07D	409/06		
	WO 00/32189	Jun 08, 2000	WIPO	A61K	31/415		
	WO 00/40087	Jul 13, 2000	WIPO	A01N	31/40		
	WO 00/56348	Sep 28, 2000	WIPO	A61K	35/78		
	WO 01/03676	Jan 18, 2001	WIPO	A61K	9/48		
	WO 01/10443	Feb 15, 2001	WIPO	A61K	31/4745		
	WO 01/47495	Jul 05, 2001	WIPO	A61K	9/14		

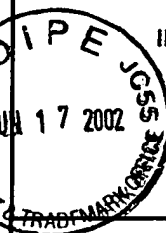
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	Ansel et al., ed. <u>Pharmaceutical Dosage Forms and Delivery Systems</u> , 6 th ed., Williams & Wilkins, Baltimore, MD, pp.176-182. (1995).
	Megrab et al. Ostradiol permeation through human skin and silastic membrane: effects of propylene glycol and supersaturation. <u>Journal of Controlled Release</u> , 36, pp. 277-294. (1995).
	United States Pharmacopeia, 24 th ed., 2254-2304. (2000).

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Form PTO-1449 (R v. 8-88)		U.S. Department of Commerce Patent and Trademark Office		Attorney Docket No. C-3407/1/U.S.	Serial No. 10/047,222
 INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)				Applicant Gao et al.	
				Filing Date January 15, 2002	Group No. 1614
				OTHER DOCUMENTS (Including author, title, date, pertinent pages, etc.)	
		Usui <i>et al.</i> Inhibitory effects of water-soluble polymers on precipitation of RS-8359. <i>International Journal of Pharmaceutics</i> , 154, pp. 59-66. (1997).			
		Usui <i>et al.</i> Dissolution improvement of RS-8359 by the solid dispersion prepared by the solvent method. <i>International Journal of Pharmaceutics</i> , 170, pp. 247-256. (1998).			
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